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PATENT	THE PROPERTY OF	

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re patent application of:

David A. WILLIAMS, et al.

Serial No. 10/705,561

Filed: November 11, 2005

METHODS FOR ENHANCED

RETROVIRAL-MEDIATED GENE

TRANSFER USING MOLECULES

WITH VIRUS-AND CELL BINDING

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Date of Signature

Group Art Unit 1633

INFORMATION DISCLOSURE STATEMENT

MAIL STOP AMENDMENT Commissioner for Patents PO Box 1450 Alexandria, VA 22313-1450

Sir:

Pursuant to the provisions of 37 CFR 1.56, 1.97, and 1.98, Applicant requests consideration of the references listed on the attached PTO/SB/08 forms and/or the additional information identified below.

A legible copy of each foreign patent document and publication listed on the PTO/SB/08 form is enclosed.

For each non-English language reference listed on the attached SB/08 form, reference is made to:

Japanese Patent No. 2-97397 corresponding to European Patent Application Publication

No. 0 349 342 A2, a copy of which is also enclosed.

Japanese Publication No. 2-311498 corresponding to Kimizuka et al. U.S. Patent No.

5,102,988, and European Patent Application Publication No. 0 399, 806 A2. A copy of the

European publication is enclosed.

This Information Disclosure Statement is submitted before the first Office Action on the

merits, and thus no certification and/or fee is required. Should any other fee be required,

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payment of issue fees.

The filing of this Information Disclosure Statement shall not be construed as an admission

that the information cited is, or is considered to be, material to patentability as defined in

§1.56(b).

Respectfully Submitted,

Bv:

John J. Emanuele, Jr.

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Information Disclosure Statement Serial No. 10/705,561

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Approved for use through 10/31/2002. OMB 0651-0031 U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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	1,1-1,1-1,		01-1988	Binder			П			
			06-	01-1989	McCarthy					
		4,980,27	9		12		Peters			
		5,004,68	1		04	02-1991	Boyse			
		5,019,64	6		05-	5-28-1991 Furcht				
		5,102,98	8		04-	07-1992	Kimizuka			7
		5,116,36	8		05-	26-1992	McCarthy			٦
		5,124,15	5		06-	23-1992	Reich			
		5,175,09	6		12-	29-1992	Hook			7
ÞΛ		5,188,95	9 - 🚎 -		02-	23-1993	Haberman	: . # * · · · · · · · · · · · · · · · · · ·	-1 (4) (A)	-;;
		5,198,42	3		03-	30-1993	Taguchi			7
		5,229,17	2	A 1	07-	20-1993	Cahalan et al			
			03-	29-1994	Badger					
<u> </u>		5,354,68	6		10	11-1994	Haberman			
		5,405,77	2		04	-11-1995	Ponting			
		5,409,82	5		04	-25-1995	Hoffman			1

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Initials*			de- Nun	ber-Kind Code ⁵ (if known	MM-DD-YYYY		Document Figures Appear			
_		EP 0 349	342	A2	01-03-1990	Takara Shuzo Co. Lt				
		EP 0 399	306	AI	11-28-1990	Taguci	hi		\Box	
		JP 2 31149	98		12-01-1989	Takara	Shuzo Co. Lt		口	
		JP 2 9739	7		09-04-1990	Takara	Shuzo Co. Lt		口	
		WO 90/13	641		11-15-1990	Sloan-	Kettering		\Box	
		WO 93/18	137	Al	09-16-1993	System	nix Inc.		P	
		WO 94/02	610		02-03-1994	Dana-I	Farber Cancer		P	
		WO 95/26	200		10-05-1995	Indian	university F			

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				sion and the Extrace ning Co., New York	llular Matrix", Molecular Biolo	gy of the Cell, 19	83, pp. 673-713,	
		"Bubble	Boy sa	ved by gene therapy	", BBC News, April 3, 2000			
		ANDER	SON, F	., "Human Gene The	rapy", Nature, Apr. 30, 1998,	Vol./Issue No. 39	92 Supp., pp. 25-30	
		ANDER No. 256	SON, W , pp. 80	8, 1992, Vol./Issue				
		ANDER	SON, W	/. FRENCH, "Prospe	cts for Human Gene Therapy	r ^{t1} ,		
		Hemato	poietic (al Gene Transfer of Human A ectable Marker Sequences on			
		ASHWE	LL, G. I	ET AL., "Carbohydra 51, pp. 531-554	te-Specific Receptors of the I	iver", Ann. Rev.	Biochem, 1982,	
				AL., "Lymphoid Pred /Issue No. 105, pp. 4	ecursor Cells Adhere to Two Different Sites on Fibronectin", J. Cell . 489-498			
		of in vitr	o activa	ted progenitors witho	ne transfer into hematopoieti out marrow ablation", Proc. N	atl. Acad. Sci. US	SA, 1994, Vol./Issue	
		BODINE Rhesus into CD	, D.M. I Monkey 34+ Bon	ET AL., "Long-term i Hematopoletic Cell Le Marrow Cells" Blo	n vivo expression of a Murine s of Multiple Lineages After R and 1993, Vol./Issue No. 82:7	tetroviral-mediate	d Gene Transfer	
		BODINE Gene Ti	, DAVII ansfer i	D M., ET AL., "Devel	opment of a High-Titer Retro Hematopoietic Stem Cells", I	virus Producer Ce	ell Line Capable of	
		BRADL	Y, T.R.		th of Mouse Bone Marrow Ce 7-300	lls in Vitro", Aust.	J. Exp. Biol. Med.	
					cal Cord Blood Hematopoieti ood Cells, 1991, Vol./Issue N			
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•				H.E. ET AL., "The fu , pp. 321-329	ture of Umbillical Cord Trans	portation", Umbili	cal Cord Blood		
					splantation of Canine Long-T ctors", Blood, 1992, Vol./issu				
		CORNET gene-tran	ısfer: i	mplications for huma	lfate as an effective alternativ an gene therapy", Journal of \	e to polybrene in /irological Metho	retroviral-mediated ds, 1989, Vol./Issue		
		CRISTIA	NO, R. livery a	J., ET AL., "Hepatic and Expression in Pri	Gene Therapy: Adenovirus E mary Hepatocytes", Proc. Na				
		DILBER,	MS. E emator	T AL., "Basic fibrobla	ast growth factor increases re od progenitor cells", Exp. Her				
		EMONS,	G. ET		einizing Hormone Releasing eprod., 1994, Vol./Issue No. 9				
		FICHARD No. 14, p	DET A p. 515-	L., "Another Look at 531	Collagen V and XI Molecules	", Matix Biology,	1994, Vol./issue		
			ion wit		ed resistance to taxol for peripheral blood progenitor cells following ing retroviral vector", Exp. Hematol., 1995, Vol./Issue No. Abstract				
		Blood Pro	ogenito	r Cells After Introduc	x Vivo Expansion and Select tion of a Mutated Dihydrofola 995. Vol./Issue No. 85:2. pp.	te Reductase cD			
			ANN, T		ss Toward Human Gene The		June 1989, pp.		
		Principles	of Ge		Somatic-Cell Tene Therapy lo. Chapter 24 Genetic Engin				
		GLUCKM	AN, E.	ET AL., "Bone Marr No. 45, pp. 557-564	ow Transplantation in Fancor	ni Anaemia*, Briti	sh J. of Haem.,		
			adhes	ion in fibronectin ass	d efficient transduction of prir sisted gene transfer", Blood, 1				
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		1994, Vo	I./Issue	No. 10:2, pp. 114,			•		
		Nature B	otechn	iology, 1996, Vol./Is:	/irosomes: Cationic Liposome sue No. 14, pp. 339-342		•		
		Hematolo	gy, 19	93, Vol./Issue No. 3	Elusive Peripheral Blood Hem 0:4 Supp. 4, pp. 82-89				
		deaminas	se defic	ciency", Gene Thera	Bone marrow gene transfer in py, 1996, Vol./Issue No. 3, pp	o. 179-183			
l		Breast Ca	ancer,	The Lancet, 1995, \	a Specific Antioestrogen (ICI /ol./Issue No. 345, pp. 29-30				
		HOWS, J Lancet, J	.M. ET uly 11,	AL, "Growth of hum 1992, Vol./Issue No	nan umbilical cord blood in lor . 340, pp. 73-76	ngterm haemopo	ietic cultures",		
		KARLSS(Transfer",	ON, ST , Blood	EFAN, "Treatment of 1991, Vol./Issue N	of Genetic Defects in Hemato o. 78:10, pp. 2481-2492	poietic Cell Fund	ction by Gene		
		KASAHA Interactio	RA, N. ns", Sc	ET AL., "Tissue-Speience, 1994, Vol./Iss	ecific Targeting of Retroviral Vectors Through Ligand-Receptor sue No. 266, pp. 1373-1376				
		KIMIZUK/ Expresse	A ET A d in Es	L., "Production and cherichia coli", J. Bi	Characterization of Functions ochem., 1991, Vol./issue No.	of Domains of Hu 110:2, pp. 284-2	man Fibronectin 291		
		KLIJN, J. Hum. Rep	G.M. E prod., 1	T AL., "Pre-Clinical a 994, Voi./Issue No.	and Clinical Treatment of Bre 9 Supp. 1, pp. 181-189	ast Cancer With	Antiprogestins",		
·		KOHLI-KU Using HL 419-422	JMAR, A-Matc	M. ET AL., "Haema hed Sibling Umbilica	topoietic Stem/Progenitor Ce al Cord Blood Cells", British J	il Transplant in F . Haem., 1993, V	anconi Anaemia /ol./issue No. 85, pp.		
		KOHN, Do Opinion in	Pedia	trics, 1995, Vol./Issu					
		KORNBLI generate 1759	HTT, A at least	A.R., ET AL, "Primar t 10 polypeptides fro	y structure of human fibroned m a single gene", EMBO J.,	tin: differential s 1985, Vol./Issue	plicing may No. 4:7, pp. 1755-		
Examiner Signature						Date Considered			

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		Tibronecti	n", Pro	c. Nati. Acad. Sci. U	on and characterization of cD JSA, 1983, Vol./Issue No. 80:	11, pp. 3218-32	22	
		Abstract	oy an ir 3/1_pp	iternal segment cod 221-226	n fibronectin: molecular cloni. ling for a structural domain", E	MBO J., 1984, \	/ol./Issue No.	
		No. Abstr	de chai	ins differing in the ni '14. pp. 5853-5868	n fibronectin: cell specific alte umber of internal repeats", Nu	cleic Acids Res.	, 1984, Vol./Issue	
		7:10 pp.	3459-3	me in Murine Hema 1465	ed Gene Transfer of Human A topoletic Stem Cells in Vivo",	Mol. Cell. Biol.,	1987, Vol./Issue No.	
		no 8892-	s-Intect 8896	ted Hematopoletic S	n Of Human Adenosine Deam Stem Cells", Proc. Natl. Acad.	Sci. U.S.A., 198	9, Vol./Issue No. 86,	
		pp. 288-3	01 		ytoadhesion Molecules", Exp.		•	
		with high of fanconi	etticien Lanemi	icy by a retroviral ve la complement c de	or cells purified from cryopres octor and expanded ex vivo wil ne" Blood 1994 Vol./Issue N	th stable integral	tion and expression	
		LUSKEY, Mediated 396-402	B.D., I Gene	ET AL., "Stem Cell F Transfer Into Murine	Factor, Interleukin-3, and Inter Hematopoietic Stem Cells", t	leukin-6 Promot 3lood, 1992, Vol	e Retroviral- ./Issue No. 80:2, pp.	
		Line", Viro	ology, 1	1988, Vol./Issue No.				
_		Different i	Jasmio	is", J. Virol., 1988, \ ———————	ackaging Line for Gene Trans /ol./Issue No. 62:4, pp. 1120-	1124		
		MCGLAVI marrow m	E P. ET	FAL., "Interaction of vironment", Blood C	f primitive human myeloid and ells, 1994, Vol./Issue No. 20:1	lymphoid proge , pp. 121-128	ntors with the	
		Glycopept	tide Lig 12-620	and for the Asialogh	ed Delivery of DNA Using YEE ycoprotein Receptor", Bioconj	ugate Chem., 19	994, Vol./Issue No.	
MILLER, A. DUSTY, "Human Gene Therapy Comes of Age", Nature, June 11, 1992, Vol./Issue 357, pp. 455-460								
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		Human E 1399	one M	arrow Lon	g-Term Cu	nal Support Enhances Cell-F ulture-Initiating Cells", Blood,	1992, Vol./Issue	No. 79:6, pp. 1393-		
		Abstract:	Dublin	, Ireland, S	Sept. 18-2	apy: New Frontiers, an Interr 1, 1994, pp. 1-2		. •		
		Blood Ce	lis, 199	94, Vol./Iss	sue No. 20	expansion of cord blood-deri , pp. 468-481, Meeting Abst	ract			
		Hematop	ORITZ, T. ET AL., "Bone Marrow Extracellular Matrix Molecules Improve Gene Transfer into Human ematopoletic Cells via Retroviral Vectors", J. Clin. Invest., 1994, Vol./Issue No. 93, pp. 1451-1457							
		Genetic 1 No. 178	herapi	es Of Sev 9-536	ere Combi	lood Cells as Targets For G ined Immunodeficiency Dise	ase", J. Exp. Med	i., 1993, Vol./issue		
		Paradox"	The F	rotein Fol	ding Probl	ational Complexity, Protein S em and Tertiary Structure Pr	ediction, 1994, p	p. 491-495		
		NOJIMA, 105-kD P	YOSH rotein"	IHISA ET , J. Exp. M	AL., "Liga led., 1992,	tion of VLA-4 on T Cells Stin Vol./Issue No. 175, pp. 104	nulates Tyrosine I 5-1053	Phosphorylation of a		
-		Glucocen Bone Mar	ebrosid	iase Gene ansduced	in Mice ar	efer and Sustained High Exp nd Their Functional Macroph oviral Vector". Proc. Natl. Ac- eukin-2 Secreting melanoma	ages Following T	ransplantation of		
		Metastaic	Tumo	r", Human	Gene The	erapy, 1994, Vol./Issue No. 5	, pp. 577-584			
		Differentia	ation",	Science, 1	1984, Vol./	f Murine Erythroleukemia Co Issue No. 224, pp. 996-998				
		PATEL, V Character	P. ET	AL, "The and Deve	Fibronecti elopmental	n Receptor on Mammalian E Regulation", J. Cell Biol., 19	rythroid Precurso 86, Vol./Issue No	or Cells: o. 102, pp. 449-456		
REISBACH, G. ET AL., "Characteriz expressing c-kit", Exp. Hematol., 199						ation of hemopoietic cell pop 3, Vol./Issue No. 21, pp. 74	oulations from hur -79	man cord blood		
		RIDDELL lymphocy	STAN tes in h	ILEY ET A IIV-infecte	L., "T-cell ed patients	mediated rejection of gene- ", Nature Medicine, 1996, Vo	modified HIV-spe ol./Issue No. 2:2,	cific cytotoxic T pp. 216-223		
Examiner Signature							Date Considered			

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		3/5-413			s Receptors*, Ann. Rev. Biod				
		ivietnoas	in Enzy	/mology, 1982, Vol./	ification, Immunochemical Pr Issue No. 82, pp. 803-831				
		Bio. Cher	n., 198	11, Vol./Issue No. 25			·		
		of metast	ic meia	inoma cells to Lamii	ect of fibronectin and its recombinant polypeptides on the adhesion nin", Jpn. J. Cancer Res., 1991, Vol./Issue No. 82, pp. 1112-1119				
		Biochemi	wesser strv19	nger RNAs Possibly 386. Vol./Issue No. 2	rer Fibronectin Complementa Encoding the α and β Subur 25. pp. 4936-4941	its of Plasma Fil	pronectin",		
		53, pp. 53	31-537		ed Targets for Retrovirus Inte				
		Hormone- 3095	-Geloni	in Conjugate", Journ	xins: Preparation and Charac al of Biological Chemistry, 19	989, Vol./issue N	o. 264:6, pp. 3089-		
		Retrovial	ranste	er of Human MDR1"	Selection of Drug Resistant B , SCIENCE, July 3, 1992, Vo	l./Issue No. 257,	pp. 99-100		
		initiating t	ong-1	erm Hematopoiesis	ation and Partial Purification In Vitro", Blood, 1989, Vol./Is	sue No. 74-5, pp	. 1563-1570		
		Homolog	ells Se of the S	ectively Expressing	n Hematopoiesis in Long-Ten the Membrane-Bound and S Stem Cell Factor" Proc. Nat	ecreted Forms	of the Human		
		Oncology	Nover	nber 1994, Vol./Issu	Post-chemotherapy Tamoxif e No. 8/11, pp. 39-43	en in Early Breas	st Cancer",		
		TORRE, I	D. ET A	L., "Interaction of his virus", Fems. Imm	uman plasma fibronectin with nunol. Med. Microbiol., 1994,	viral proteins of Vol./Issue No. 8	human -2, pp. 127-131		
		TSAI, SCI fibroblasts	HWICK and fil	WANN ET AL., "Dif bronectin", Blood, 19	ferential binding of erythroid a 987, Vol./Issue No. 69-6, pp.	and myeloid prog 1587-1594	enitors to		
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		Envelope 68:7 pp	Protei 4609-4	n to Redirect : 1619	the Ho	"Modifications in the Binding ost Range of Retroviral Vector	rs", J. Virol., 1994	I, Vol./Issue No.		
		Rhesus N USA, 199	/lonkey 22. Vol	s Transplante /Issue No. 89	d with	"Long-Term Expression of Hu Retrovirus-Infected Bone-Ma 640-7644	errow Cells", Proc	. Natl. Acad. Sci.		
		Fibronect	lin", Ex	perimental He	matol	nerence of Murine Hematopoli ogy, 1994, Vol./Issue No. 22,	pp. 1236-1243	bsets to		
			ė.			', SCIENCE, June 10, 1988, p				
		Into Sing	le Line: in" J	age Clonogen Exp. Med. 19	ic Prog 91. Vo	entiation of Primitive Human N genitors is Accompanied by A ol /Issue No. 174, pp. 693-703	Iterations in The	ir Interaction with		
·		VERMA, 389, pp. 2	IM ET.	AL., "Gene the	erapy-	promises, problems, and pro-	spects", Nature,	1997, Vol./Issue No.		
						ation of Umbilical Cord Blood 92, Vol./Issue No. 79:7, pp. 1		ive Therapy:		
		WAGNER patients",	R, J.E. Blood	ET AL., "Allog 1993, Vol./Is	enic u sue N	umbilical cord blood transplantation: Report of results in 26 No. Abstract, pp. 82-86a				
		WATT ET	ΓAL., " n in Hu	Adhesion Red man Thymus	eptor	s are differentially expressed erimental Hematology, 1992,	on Developing Th Vol./Issue No. 20	nymocytes and 0, pp. 1101-1111		
		Deamina	se", Bio	ochemistry, 19	86, V	olete Sequence and Structure ol./Issue No. 25, pp. 8234-82	44			
		WILLIAM Interactio	S, DA\ ns", Na	/ID A. ET AL., iture, 1991, V	Fibro	onectin and VLA-4 in Haemat ue No. 352, pp. 438-441	opoietic Stem Ce	ell-Microenvironment		
WILLIAMS, DAVID A. ET AL., "Umb New Therapeutic Approaches to Soi 504-516						pilical Cord Blood Stem Cells matic Gene Therapy", Blood	as Targets for Ge Cells, 1994, Vol./	enetic Modification: Issue No. 20, pp.		
		XIAO, M.	ET AL on culti	., "Extensive pure", Blood Ce	rolifer Ils, 19	rative capacity of single isolat 194, Vol./Issue No. 20, pp. 45	ed CD34 human 5-467	cord blood cells in		
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		XU, L.C., ET AL., "Long-term in vivo expression of the human glucocerebrosidase gene in nonhuman primates after CD34+ hematopoletic cell transduction with cell-free retroviral vector preparations", Proc. Natl. Acad. Sci. USA. 1995. Vol./Issue No. 92, pp. 4372-4376							
		XU, LINCHENG, ET AL., "Correction of the enzyme deficiency in hematopoletic cells of Gaucher patients using a clinically acceptable retroviral supernatant transduction protocol", Experimental Hematology, 1994. Vol./Issue No. 22, pp. 223-230							
		YAO ET AL., "Primary myoblast-mediated gene transfer: persistent expression of human factor IX in mice", Gene Therapy, 1994, Vol./Issue No. 1:2, pp. 99-107							
		ZIEGLER, B.L. ET AL., "Phenotype analysis of umbilical cord (CB) blood CD34 cell subpopulations", Blood, 1992, Vol./Issue No. 80 Supp. 1, pp. 408A							

Examiner Signature	·	Date Considered	

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